

# Exhibit 23

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY  
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5

6 IN RE: BENICAR : MDL NO. 2606  
7 (OLMESARTAN) PRODUCTS :  
8 LIABILITY LITIGATION :  
9  
10 - - -

11 February 7, 2017  
12 - - -  
13  
14 PROTECTED INFORMATION  
15 - - -  
16  
17 Oral expert deposition of  
18 STEPHEN M. LAGANA, M.D., taken pursuant  
19 to notice, was held at the law offices of  
20 Robins Kaplan LLP, 601 Lexington Avenue,  
21 Suite 3400, New York, New York, beginning  
22 at 10:09 a.m., on the above date, before  
23 Kimberly A. Cahill, a Federally Approved  
24 Registered Merit Reporter and Notary  
Public.

21  
22 GOLKOW TECHNOLOGIES, INC.  
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24 deps@golkow.com

	Page 354	Page 356
1	A. Yep.	1 MR. PARKER: Okay. Fair
2	Q. What does that mean, 4.82?	2 enough.
3	A. It means that if we take the	3 BY MR. PARKER:
4	other ARB users to be the controls, if we	4 Q. Doctor, I want to change
5	said 1 out of -- these are made-up	5 subjects in the time I have left and move
6	numbers and totally inaccurate, but if we	6 around a little bit.
7	said 1 out of a hundred patients taking	7 A. Sure.
8	an ARB other than olmesartan were	8 Q. Do you have an understanding
9	hospitalized with a discharge diagnosis	9 of what is meant by the Bradford Hill
10	of celiac disease, 4.82 olmesartan users	10 criteria?
11	would be hospitalized with a discharge	11 A. I do.
12	diagnosis of celiac disease.	12 Q. Those criteria are not
13	Q. A fourfold increase	13 addressed, not mentioned, in your report;
14	according to these data?	14 correct?
15	A. Almost five.	15 A. Not specifically, no.
16	Q. Almost five.	16 Q. Have you ever published a
17	Doctor, in terms of the	17 paper of any type in which you used the
18	number of files examined, how does this	18 Bradford Hill criteria to arrive at a
19	study compare with the Mini-Sentinel?	19 conclusion of whether cause and effect
20	A. The number of patient years	20 relationship existed between a drug and
21	examined, you're asking?	21 an outcome?
22	Q. Patient years or files out	22 A. I think that the Bradford
23	of which the analysis in the	23 Hill criteria is something that we learn
24	Mini-Sentinel was done -- let me back up.	24 about in medicine and think about when
	Page 355	Page 357
1	Do you know how the Mini-Sentinel was	1 we're evaluating those questions, but
2	done?	2 I've never -- I've never, you know,
3	A. I wouldn't say I know	3 specifically written a paper in which I
4	exactly how it's done, no.	4 looked at each point and made a response.
5	Q. So you can't compare the	5 Q. I take it from your last
6	size of the database that the FDA was	6 answer that in the period of time that
7	looking at to arrive at their conclusions	7 you were writing your general causation
8	compared to what the French folks were	8 report, you were aware of and understood
9	looking at.	9 the Bradford Hill factors criteria.
10	A. I was not going to make that	10 A. I was familiar with the
11	comparison, no.	11 criteria.
12	Q. Okay.	12 Q. And what is their use in
13	Isn't the result obtained	13 medical science?
14	for celiac disease by the French people	14 A. They are a set of questions
15	looking at their French data for	15 which are used to address cause and
16	olmesartan compared to other ARBs	16 effect.
17	inconsistent with the FDA's analysis in	17 Q. Can you explain for me why
18	the Mini-Sentinel on celiac disease?	18 that methodology was not used in your
19	MR. SLATER: Objection;	19 report?
20	foundation.	20 A. I think it influences my
21	(Pause.)	21 thinking, those points influence my
22	THE WITNESS: I don't see	22 thinking. I didn't explicitly go through
23	the Mini-Sentinel here. I don't	23 them because -- I don't know. Just did
24	know.	24 not do that.

Page 402	Page 404
<p>1 causation, if that was the only thing 2 that changed. 3 Q. You were asked by counsel a 4 few minutes ago about a hypothetical 5 where he said a patient is assumed to 6 have taken olmesartan for two years and 7 then after two years develops diarrhea 8 that lasts for two days and, after those 9 two days are up, the person stops taking 10 olmesartan for whatever reason. 11 First question on that 12 person, would the differential diagnosis 13 -- if you were looking back 14 retrospectively to try to figure out what 15 had caused the diarrhea, would the 16 differential include olmesartan 17 enteropathy? Yes or no. 18 A. Yes. 19 Q. If you wanted to be more 20 sure of that at the time, when the person 21 stopped taking the drug and then got 22 better, would an endoscopy provide 23 information if the person had had an 24 endoscopy at that time?</p>	<p>1 diagnosis of malabsorption) are strong 2 arguments in favor of causality." 3 Is that statement of any 4 significance to you? 5 A. Well, yeah, I think it's a 6 -- it's a strong statement. They're 7 applying the Bradford Hill criteria 8 there, or at least some of them, and I 9 think that -- well, they've said it quite 10 plainly, that their findings are strong 11 evidence in favor of causality, and I 12 agree with that. 13 Q. You mentioned -- 14 A. And by the way, if I could 15 just mention another thing about this 16 study -- 17 Q. Sure. 18 A. -- which I don't think that 19 we got to too specifically, when you look 20 at the strength of the association, the 21 relative risk of 5 or 10 as is seen after 22 two years of therapy on olmesartan, 23 that's a very high relative risk. 24 Q. And why is that significant?</p>
<p>1 A. It certainly could, yeah. 2 Q. Could potentially. 3 A. Uh-hum. 4 Q. Would a rechallenge 5 potentially provide important information 6 as well if someone wanted to be sure -- 7 you know, you got better after two days. 8 Would giving the drug to the person again 9 and seeing whether it recurs, would that 10 be helpful information? 11 A. It would. 12 Q. And depending on the 13 findings, that would be clinical 14 information that would be factored into 15 an ultimate diagnosis? 16 A. It would. 17 Q. Now, looking at the Basson 18 article -- I'm just going to turn to it 19 real quick -- and looking at page 5 of 20 the article, and there's a statement here 21 on the top left, "The strength of the 22 association and the consistency with 23 reported cases (including the long lag 24 time between initiation of olmesartan and</p>	<p>1 A. Well, again, getting back to 2 the -- if we think about the Bradford 3 Hill criteria, the strength of the 4 association, the fact that there's a 5 tenfold increased risk is strong. 6 Q. And, you know, you've 7 mentioned the Bradford Hill criteria. 8 Counsel had asked you if it was 9 specifically mentioned in your report. 10 You didn't actually name that criteria; 11 correct? 12 A. That's true. 13 Q. Were you fully familiar with 14 that criteria when you did your report? 15 A. Yeah -- 16 MR. PARKER: Objection. 17 MR. SLATER: Let me ask the 18 question again. 19 BY MR. SLATER: 20 Q. Were you familiar with the 21 Bradford Hill criteria when you did your 22 analysis and wrote your report in this 23 case? 24 A. Yeah.</p>

Page 406	Page 408
<p>1 Q. Okay.</p> <p>2 Even though it was not</p> <p>3 named, did you take into account the</p> <p>4 factors in the Bradford Hill criteria in</p> <p>5 doing your analysis of the available</p> <p>6 information that you relied on in forming</p> <p>7 your opinion?</p> <p>8 MR. PARKER: Objection.</p> <p>9 MR. SLATER: You can answer.</p> <p>10 THE WITNESS: Okay. I think</p> <p>11 that those factors are fundamental</p> <p>12 to how people in medicine think</p> <p>13 about medical science, and</p> <p>14 certainly I did think about them</p> <p>15 and I did address them, although</p> <p>16 not in the context of listing the</p> <p>17 criteria point -- on a</p> <p>18 point-by-point basis. But, yeah,</p> <p>19 I did think about them and I did</p> <p>20 try to incorporate them.</p> <p>21 MR. SLATER: And I'm just,</p> <p>22 for the record, going to give you</p> <p>23 a list of the Bradford Hill</p> <p>24 criteria.</p>	<p>1 putting that all together, did you</p> <p>2 incorporate analysis of those factors</p> <p>3 that was implicit into your analysis of</p> <p>4 this material?</p> <p>5 MR. PARKER: Objection.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Coming back to the Basson</p> <p>9 article, towards the end at the bottom of</p> <p>10 page 5, there's a statement that says,</p> <p>11 "Patients treated with olmesartan should</p> <p>12 be informed about the risk of this</p> <p>13 complication, and should be advised to</p> <p>14 seek medical attention if they experience</p> <p>15 gastrointestinal symptoms. This</p> <p>16 information should also be widely</p> <p>17 delivered to physicians of all</p> <p>18 disciplines, particularly to</p> <p>19 gastroenterologists who are faced to this</p> <p>20 new category of patients."</p> <p>21 In the context of a question</p> <p>22 of whether there's -- whether the authors</p> <p>23 in this article had a viewpoint on</p> <p>24 causation, is that statement I just read</p>
<p>1 BY MR. SLATER:</p> <p>2 Q. Strength of association,</p> <p>3 consistency, specificity, temporality,</p> <p>4 biologic gradient, plausibility,</p> <p>5 coherence, experimental evidence, and</p> <p>6 analogy, is that one way to describe</p> <p>7 those criteria?</p> <p>8 MR. PARKER: Objection.</p> <p>9 THE WITNESS: Yes, I believe</p> <p>10 so.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And I'll actually -- counsel</p> <p>13 objected, so I'm going to read you -- I'm</p> <p>14 going to ask you a different question.</p> <p>15 With regard to the Bradford</p> <p>16 Hill criteria, I'm going to list what I</p> <p>17 believe to be some of those factors and</p> <p>18 -- well, actually, you know what? I</p> <p>19 don't need to go through it again.</p> <p>20 Are you familiar with the</p> <p>21 Bradford Hill criteria factors?</p> <p>22 A. Yes.</p> <p>23 Q. In analyzing, for example,</p> <p>24 the literature and your experience and</p>	<p>1 to you of any significance?</p> <p>2 MR. PARKER: Objection.</p> <p>3 MR. SLATER: You can answer.</p> <p>4 THE WITNESS: Okay. I don't</p> <p>5 think there's really any vagary to</p> <p>6 that statement. I think that</p> <p>7 they're expressly stating that</p> <p>8 this is a new category of patient</p> <p>9 that we're now aware of. I think</p> <p>10 that they're saying this</p> <p>11 information is important, to be</p> <p>12 widely distributed. And I</p> <p>13 absolutely agree.</p> <p>14 The patients that we've seen</p> <p>15 at Columbia who suffered from this</p> <p>16 condition have been in terrible</p> <p>17 shape. Many have had</p> <p>18 life-threatening illness. And</p> <p>19 there's a million</p> <p>20 antihypertensives on the market.</p> <p>21 I -- you know, very rarely do you</p> <p>22 see this degree of improvement,</p> <p>23 both pathologically and</p> <p>24 clinically, with a fairly simple</p>